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Support for new clam 20 can be found at page 24, third full paragraph to page 26, as well as, inter alia, page 27-28, claim 15, Example 9, and elsewhere in the application.

It is respectfully submitted that new claim 20 is a member of the Examiner's Group IV, in that it is drawn to a method for detecting the presence of or the predisposition for a CAG repeat disorder for determining the level of expression of PDE10A RNA in an individual relative to a predetermined control level of expression. One skilled in the art will readily appreciate that the level of expression of PDE10A RNA may be measured by detecting the level of PDE10A polypeptide in an individual relative to a predetermined control level of PDE10A polypeptide.

ELECTION WITH TRAVERSE

The Examiner has required restriction to one of the following inventions under 35 U.S.C. 121:

I. Claims 1-7, drawn to a composition for treating a CAG repeat disorder, comprising a compound which modulates PDE10A expression, and a method for treating a subject having a CAG repeat disorder using the same;
II. Claims 8-12, drawn to a method for identifying a compound which inhibits or promotes a CAG repeat disorder using an animal having PDE10A;
III. Claims 13-14, drawn to a method for identifying a compound which inhibits or promotes CAG repeat disorder using a host cell containing PDE10A;
IV. Claims 15-19, drawn to a method for detecting the presence of or the predisposition for a CAG repeat disorder by determining the level of expression of PDE10A RNA in an individual relative to a predetermined control level of expression.

In response to this restriction requirement, the applicant hereby elects, with traverse, to prosecute the invention of Examiner's Group IV, claims 15-20, drawn to a method for detecting the presence or the predisposition for a CAG repeat disorder by determining the level of expression of PDE10A RNA in an individual relative to a predetermine control level of expression.

The Examiner has stated that Groups I to IV are drawn to distinct and mutually exclusive methods which require different starting materials, different steps, different end results and

different technical considerations for achieving the desired end results. In response, the applicant respectfully submits that there is a unity of invention among these groups of claims, in that all claims are related to the discovery of the association between PDE10A and CAG repeat disorders.

The applicant notes that 35 U.S.C. § 121 states, in part, that "if two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions" (underlining added). The applicant requests that the restriction of the Examiner's Group I from the Examiner's Group II be withdrawn in the view of the fact that the claims of the Examiner's Group I are not independent of Examiner's Group II.

Under MPEP § 801.01, "independent" means that "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation and effect". The claims of Examiner's Group I drawn to a compound which modulates PDE10A expression and a method of treating a subject using the same are related to the claims of the Examiner's Group II drawn to a method for identifying a compound which inhibits or promotes a CAG repeat disorder by determining the relative quantity of RNA corresponding to PDE10A, which are related to the claims of the Examiner's Group III drawn to the same method using host cells, which are related to the claims of the Examiner's Group IV, drawn to a method comprising determining the level of expression PDE10A and RNA, in that all the claims of all groups are related to the discovery of the relationship between PDE10A and CAG repeat disorders.

The applicant therefor respectfully asserts that two or more independent and distinctive inventions have not been claimed in the subject application because the groups are not independent under MPEP § 802.01. The applicant therefor maintains that the claims of Groups I to Group IV are related and are not independent. Therefore, restriction is improper under 35 U.S.C. § 121.

Additionally, the applicant points out that under MPEP § 803, the Examiner must examine the application on the merits, even though it includes claims two distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; and (2) there must be serious burden on the Examiner if restriction is not required.

The applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group I drawn to a compound which modulates PDE10A expression and a method of treating a subject using the same, should reveal whether any prior art exists as to Group II drawn to a method for identifying a compound which inhibits or promotes a CAG repeat disorder by determining the relative quantity of RNA corresponding to PDE10A, which are related to the claims of the Examiner's Group III drawn to the same method using host cells, which are related to the claims of the Examiner's Group IV, drawn to a method comprising determining the level of expression PDE10A and RNA. Since there is no burden on the Examiner to examine Groups I to IV in the subject application, the Examiner should examine the entire application on the merits.

The applicant maintains that claims 1-20 define a single inventive concept. Accordingly, the applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-20 on the merits.

ELECTION OF GROUP, WITH TRAVERSE

The Examiner has indicated that the application contains claims directed to patentably distinct groups of CAG repeat disorders of the claimed invention:

(a) Huntington's disease;
(b) Parkinson's disease;
(c) Schizophrenia;
(d) Alzheimer's disease;
(e) stroke; and
(f) trauma.

In response to this species restriction requirement, the applicant hereby elects, with traverse, to prosecute the invention of Group A, drawn to Huntington's disease.

The Examiner stated that there is a lack of unity of invention among the various CAG repeat disorders, on the basis that there is no common etiology, disease progression, or systems among these diseases. As such, the Examiner asserts that the methods of treating these different CAG repeat disorders require different materials and considerations for achieving the desired therapeutic end results. The Examiner further

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states that different materials and considerations are required for identifying compounds promoting or inhibiting or diagnosing these various CAG repeat disorders.

With respect, the applicant refers the Examiner to Ross, C.A., 1997, *Neuron* 19:1147-1150, wherein a common pathogenic mechanism for CAG repeat disorders was recognized. The groups set out by the Examiner are CAG repeat disorders. Accordingly, it is respectfully submitted that there is common etiology, disease progression, and symptoms among these diseases.

The applicant maintains that under MPEP § 803, the Examiner must examine the application on the merits, even though it includes claims two distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; and (2) there must be a serious burden on the Examiner if restriction is not required.

The applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of the prior art with regard to the generic claims should reveal whether any prior art exists with respect to the distinct species of the claimed invention. Since there is no serious burden on the Examiner to examine the Groups A, B, C, D, E and F in the subject application, the Examiner should examine the entire application on the merits.

If a telephone call would be of assistance in advancing the prosecution of the subject application, the applicant's undersigned attorney invites the Examiner to telephone at the number provided below.

Yours very truly,

NOVANEURON INC.

By: _____
David J. Heller, Reg. No. 43,384
(416) 868-1482
DJH:lc
Encls.